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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/357,375	07/20/1999	MICHEL ARTHUR	0660-0155-0-	9160

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/02/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/357,375

Applicant(s)

ARTHUR ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☒ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Applicants amendment canceling claims 36, 38-41 and 43 and addition of new claims 44-49, Paper No. 24, 10/2/2002, is acknowledged. Applicants' arguments filed on 10/2/2002, Paper No. 24, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Claims 44-49 are still at issue and are present for examination.

Drawings

The drawings filed on 7/20/1999 are objected to for the reasons stated on the form PTO-948.

Claim Objections

Claims 47 is objected to because of the following informalities:

Claims 47 each recite specific "high stringency (hybridization) conditions" and "slightly stringent (hybridization) conditions" It is suggested that applicants amend the portion of the claim that recites the "slightly stringent (hybridization) conditions" such that it is clear that those conditions which are considered "slightly stringent (hybridization) conditions" are the same conditions (i.e. salt/SDS concentration) with a decrease in the temperature.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 (45 and 46 dependent on) and 47 (48 and 49 dependent on) are indefinite in that it is confusing in the recitation "... at least three of the following:" which is followed by three sub-sections (a), (b) and (c). Each of the sub-sections list protein(s) or fragments thereof. The claim is confusing because as applicants have stated that the claimed composition must comprise at least three of the following, it is unclear if it is applicants intent that the composition must comprise a protein selected from sub-section (a), sub-section (b) and sub-section (c) or can the claimed composition comprise two proteins from (a) and one from (b) or (c). Further confusion is added to the claim because applicants state "...at least three of the following:" and then only list three groups. It is suggested if it is applicants intent that the claimed composition must comprise a protein from each of (a), (b) and (c) then applicants amend the claim such as "A composition comprising [at least three of] the following: (a)...(b)... and (c)...", For the sake of advancing prosecution, this is how the claim is interpreted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brisson-Noel et al. (Antimicrobial Agents and Chemotherapy 34(5): 924-927, May 1990).

The rejection is stated in the previous office actions, Paper No. 12, 3/27/2001, and Paper No. 16, 11/2/2001, as it applied to claims 36, 38, 41 and 43.

As was stated previously, Brisson-Noel et al. teach the cloning and heterospecific expression of the resistance determinant VanA encoding high-level resistance to glycopeptides in *Enterococcus faecium* BM4147. Specifically, they teach that the transformation of a 4-kilobase *EcoRI* fragment encoding this protein conferred vancomycin resistance in *Enterococcus faecalis* and *Bacillus thuringiensis*. Brisson-Noel et al. further teach that the nucleotide sequence upstream of the vanA protein appears to be required for full expression of the glycopeptide resistance phenotype mediated by pIP816, pIP816-1 and pAT211 (See page 925, left col., lines 11-16 and Figure 2). In total Brisson-Noel et al. teach a 10 kb portion of DNA which confers vancomycin resistance in transformed bacteria.

One of ordinary skill in the art at the time of filing would have been motivated to sequence the entire isolated 10 kb DNA fragment responsible for vancomycin resistance and identify each open reading frame and express the encoded proteins such that these proteins could be used in determining the mechanism of action in determining vancomycin resistance. The motivation for the identification and purification of these additional protein determinants is given by Brisson-Noel in there statement that there appear to be additional determinants "... required for full expression of the glycopeptide resistance phenotype..." One would have had a reasonable expectation of success based on the level of skill in the art at the time with respect to protein expression and purification.

As previously, applicants traverse this rejection as it applies to claims 44-46 on the basis that Brisson-Noel et al. do not describe the nucleotide or amino acid sequences of the vanA determinant, nor does it suggest mechanisms to explain the observed resistance to glycopeptides associated with the plasma (plasmid). Applicants further argue that the reference teaches that it is not possible to identify the exact nature of the determinant present on the 4kb fragment since "additional sequences present on the 6kb EcoRI fragment appear to be required for full expression of the glycopeptide resistance phenotype...". This statement in fact leads to the motivation for the sequencing of the entire 10 kb DNA fragment, identification of all open-reading frames and production of the encoded proteins so that the "exact nature of the determinant present on the 4kb fragment" and the role it plays in vancomycin resistance can be determined. With respect to applicants arguments regarding the lack of a teaching of

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the amino and/or nucleic acid sequences of the instant claims, applicant is reminded that these are inherent properties of the proteins and nucleic acids taught by Brisson-Noel et al.

Applicants have amended the claim such that it is now directed to a composition comprising at least three proteins selected from the group consisting of: a) the protein having the sequence of SEQ ID NO: 2, b) the protein having the sequence of SEQ ID NO: 6, and c) the protein having the sequence of SEQ ID NO: 4 or SEQ ID NO: 25 or functional fragments thereof. As was stated in previous office actions and above, Brisson-Noel teach that "additional sequences present on the 6kb EcoRI fragment appear to be required for full expression of the glycopeptide resistance phenotype...". That is sequences and the encoded proteins beyond that which occur on the 4 kb plasmid. This statement in fact leads to the motivation for the sequencing of the entire 10 kb DNA fragment, identification of all open-reading frames and production of all of the encoded proteins so that the "exact nature of the determinant present on the 4kb fragment" and the role it plays in vancomycin resistance can be determined. The expression of all of the proteins encoded by the 10 kb fragment would make obvious the rejected claims drawn to a composition comprising at least three of the specified proteins or a composition comprising at least three proteins comprising a fragment of the specified proteins wherein said proteins and composition confers resistance to glycopeptides in Gram-positive bacteria.

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Remarks

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a long horizontal flourish extending to the right.

Richard Hutson, Ph.D.
Patent Examiner
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November 27, 2002